Proposal Review Committee

Terms of Reference

1. Terms of reference

The Proposal Review Committee (PRC) is an independent, impartial team of experts who provide scientific, public health, health systems, programmatic, country implementation, market dynamics, product development and health economics expertise to Unitaid on proposals submitted for funding (hereinafter Proposals) and draft grant agreement documents (hereinafter GAD documents).

1.1   Specifically, the PRC:
- Reviews Proposals according to established criteria;
- Participates in the Joint Review Committee (JRC)[1] meetings;
- Provides recommendations to the Unitaid Executive Board (EB) as part of the JRC, based on the review of the Proposals and
- Reviews the GAD documents to ensure that the JRC and the EB recommendations and comments have been duly addressed during the GAD process.

1.2   The PRC is an advisory body that does not have decision-making authority.

2. Membership

The PRC is broadly constituted and comprises Members with a firm commitment to Unitaid and the requirements of PRC membership, including:

- Serving in a personal capacity without respect to professional or institutional affiliation and without acting upon advice or representation of the interests of governments, organizations, or other third-party representatives;

- Complementary and cross-cutting expertise in areas outlined in Paragraph 2.5 below;
- Commitment to the highest standard of compliance with the Declaration of Interest Policy and Confidentiality Undertaking;
- Regular attendance and participation in PRC/JRC in-person meetings, teleconferences;
- Active, independent and high-quality engagement in discussions and processes related to the PRC mandate;
- High quality of input/recommendations;
- The total estimated average time requirement per PRC Member and per year of 20 full working days[2].

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[1] JRC is composed of the PRC and the Secretariat review teams.
[2] PRC Member yearly time commitment for attendance of at least 1 four-day JRC in-person meeting (plus in-depth review as part of the PRC core review team of 4 proposals per PRC Member on average per meeting with estimated 8 hours of total review time per proposal and 4 proposals per PRC Member on average where not part of the PRC core review team with estimated 2 hours of total review time per proposal), 2 two-day virtual/teleconference JRC meeting on average (plus in-depth review as part of the PRC core review team of 2 proposals per PRC Member on average with estimated 8 hours of review time per proposal and 2 proposals per PRC Member on average where not part of the PRC core review team with estimated 2 hours of total review time per proposal) and an average of 8 GAD reviews per PRC Member per year with 6 hours of average review time for regular GADs that have gone through the competitive selection process and 8 hours of average review time for atypical (enabler) GADs and grant extensions.

2.2   Size of the PRC

The PRC comprises up to 16 Members, in addition to the Chair and Vice-Chair. The PRC Chair and Vice-Chair will review the composition of the PRC at the end of each calendar year based on PRC Member performance assessment and request EB approval of any recommended adjustments to the PRC size and composition, if deemed necessary.

Graph1: PRC Composition within broader JRC context
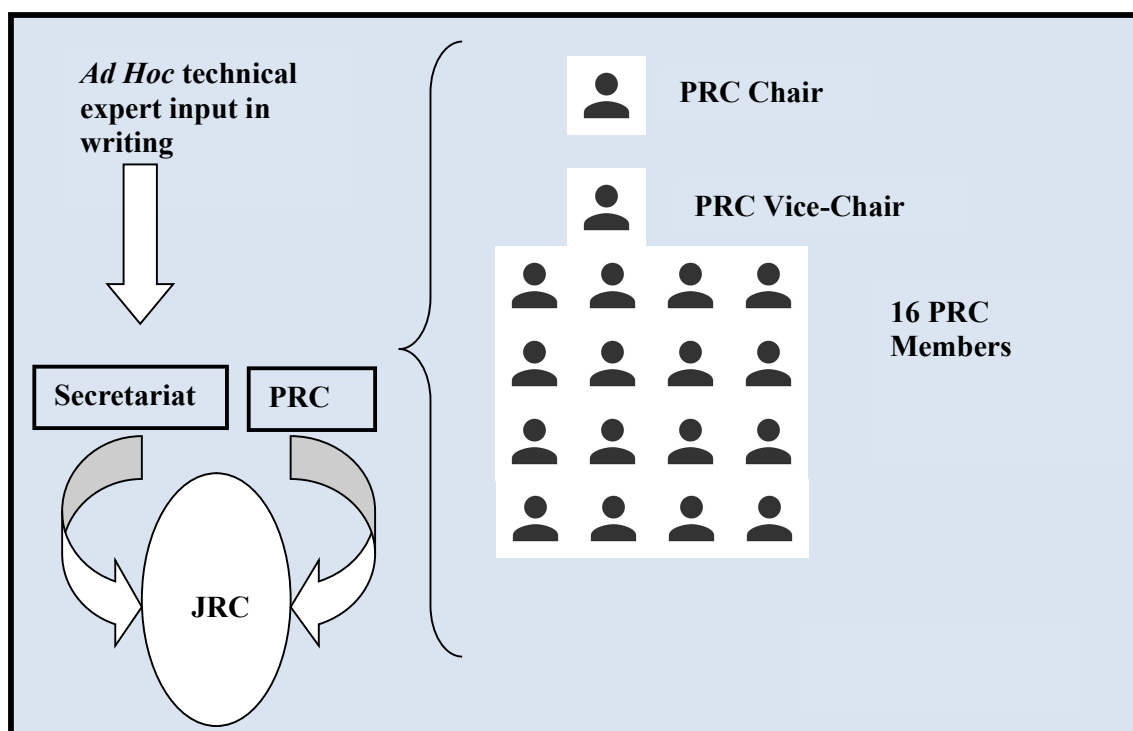
2.3   PRC Chair and Vice-Chair

The Unitaid EB selects the PRC Chair and Vice-Chair.

In the absence of the PRC Chair, or in any other circumstance where the Chair cannot effectively perform their duties, the Vice Chair will chair the PRC.

The PRC Chair and/or the PRC Vice-Chair will attend EB meetings and represent the PRC as observers and shall take the floor upon request from the EB Chair.

The following process is used for the selection of the PRC Chair and Vice-Chair:

- The Executive Board's Policy and Strategy Committee (PSC) leads the PRC Chair and Vice-Chair selection process on behalf of the EB, as the EB's PRC Nominations Sub-Committee (the Sub-Committee).
- The Sub-Committee will first consider opportunities to select the PRC Chair and Vice-Chair from amongst the currently serving PRC members. The Secretariat will therefore invite expressions of interest from the current PRC members at least four months before the end of the current PRC Chair and Vice-Chair's term of office.

- After due consideration of opportunities to select internal candidates, the Sub-Committee may consider expanding the candidate pool for the Chair position to external candidates.
- Candidates will be requested by the Secretariat to submit a letter of motivation and CV, which the Sub-Committee will assess against the following selection criteria:
  - (a) Technical skills;
  - (b) Risk of conflict of interest;
  - (c) Strategic vision for organization of the work of the PRC in response to the strategic priorities of Unitaid Strategy and emerging trends;
  - (d) Proven leadership skills and experience managing a consensus-based international expert committee; and
  - (e) Vision for ensuring the independence and impartiality of the PRC.
- In addition, when considering internal candidates, the Sub-Committee will consider the outcomes of PRC member performance assessments; and when considering external candidates, the Sub-Committee may instruct the Secretariat to request third-party references.
- The Sub-Committee will submit its recommendations to the EB.
- The PRC Chair and Vice-Chair will be appointed by the EB in a closed session.
- Appointments shall normally be for an initial term of office of three years, renewable once, subject to satisfactory performance.

2.4   Selection of Members

PRC Members are selected from a pool of applicants based on their training, skills, experience and ability to advise on areas of expertise related to the PRC mandate (see Paragraph 2.5).

The following sequential steps are followed in selecting the PRC Members:

- Unitaid Policy and Strategy Committee recommends to the EB the approval of the candidature of the PRC Chair and Vice-Chair;
- EB appoints the PRC Chair and Vice-Chair;
- Secretariat issues a call for applications;
- PRC Chair, Vice-Chair and Secretariat review applications and produce a shortlist of 20 – 24 names;
- The PRC Chair and Vice-Chair discuss the shortlisted candidates with the PSC Chair.
- The PSC recommends to the EB a shortlist of 16 PRC Member candidates and up to 6 alternate candidates[3] ;
- EB approves the new PRC composition.

The composition of the PRC reflects a geographical and gender balance, assuring representation from those resident in, or with experience of working in low and lower-middle income countries.

2.5   Expertise of PRC Members

Members of the PRC are high-level senior experts with advanced experience in their fields of work. Members have significant, demonstrated expertise and leadership in the skill sets described below. The selection of the PRC Members should ensure that all of the below areas of expertise are represented on the PRC.

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[3] 6 alternate members are considered in case the EB objects to any of the proposed candidates.

Disease-specific areas of expertise

1.	**HIV/AIDS**	Expertise in HIV, including prevention, diagnosis and treatment. This may include expertise in HIV with a perspective on future trends, and expertise in HIV-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
2.	**Tuberculosis**	Expertise in TB, including prevention, diagnosis and treatment. This may include expertise in TB with a perspective on future trends, and expertise in TB-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
3.	**Malaria**	Expertise in malaria, including prevention, diagnosis and treatment. This may include expertise in malaria with a perspective on future trends, and expertise in malaria-related global health policy and public health. Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.
4.	**HIV Co-Infections and Cross-Disease Integration**	Expertise in HIV co-infections, including prevention, diagnosis and treatment. This may include expertise in HIV co-infections with a perspective on future trends, and expertise in HIV co-infection-related global health policy and public health; Experience in enabling access to health products that address more than one disease or condition (e.g., polyvalent diagnostic platforms); Experience addressing the needs of people affected by more than one disease (e.g., treatment of co-infections); Experience reaching people for one health issue through a different program or clinical interaction (e.g., leveraging child health programs to diagnose malaria in children).
5.	**Women and children's health**	Expertise in women and children's health with a perspective on future trends, and expertise in women and children's health -related global health policy and public health. Technical expertise and skills on the principles and application of standard and innovative practices, methods and techniques in the field of women and children's health . Experience designing/implementing interventions to benefit (i) people living in developing countries, with particular attention to low-income, and lower middle-income countries; (ii) underserved groups, which are to be defined based on the specific disease context.

Access-specific areas of expertise

6.	**Market Dynamics and Health Economics**	Expertise in the market dynamics of health commodities, including price reduction strategies and market analysis. High level experience in the health economics of the pharmaceutical and/or health commodity[4] industries, including regulatory and legal issues,

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[4] Health commodity is intended to include medical devices and *in vitro* diagnostic devices.

		research incentives, competition, subsidy, costing, contracting, demand side and social marketing, public private interface.
7.	**Product Development**	Expertise in product development issues in relation to the pharmaceutical and health commodities industries, including process and product development, commercialization and product launch.
8.	**Intellectual Property**	Expertise in intellectual property issues, including international legal and policy frameworks (such as the TRIPS Agreement) and their implications for access to health commodities for HIV/AIDS, TB, malaria, co-infections and RMNCH.
9.	**Supply Chain**	Expertise in supply chain management, pharmaceutical supply, procurement of pharmaceutical products and medical devices and related health commodities, in particular in developing countries.
10.	**Regulation**	Expertise in the regulation of health products, including work with Stringent Regulatory Authorities (SRAs) or the WHO pre-qualification process.
11.	**Scalability and Country Implementation**	Experience of scaling up successful projects and ensuring transition after the end of the project. Experience of programmatic implementation in developing countries, good understanding of their political and institutional systems and experience collaborating with civil society and development partners (including in demand creation).
12.	**Community Demand Generation**	The expertise involves identifying and addressing the specific health needs and concerns of different communities, understanding the behavioral drivers and barriers that influence health- seeking behaviors, designing and implementing demand generation programs that are evidence-based and context-specific and working collaboratively with community stakeholders, to co-produce health interventions.
13.	**Local/regional manufacturing of health products**	The expertise includes understanding the entire manufacturing process, from raw material sourcing to final product packaging. It also involves knowledge of Good Manufacturing Practices (GMP) and regulatory requirements specific to the health products being produced. The expertise also requires the knowledge of how to effectively transfer technology from global manufacturers to local or regional facilities, maintain stringent quality control and assurance processes, efficiently managing the supply chain, complying with local, regional, and international regulations and developing sustainable manufacturing practices with due consideration of climate issues.
14.	**Climate and health**	The expertise involves understanding how climate change affects weather patterns, ecosystems, and the frequency and intensity of extreme weather events like heatwaves, hurricanes, floods and how these climate changes directly and indirectly affect human health, including the spread of infectious diseases, respiratory issues from air pollution, and mental health challenges. It also includes identifying populations and regions most at risk from climate-related health impacts, such as vulnerable communities and small island developing states and developing strategies to reduce greenhouse gas emissions from health systems and health products and enhance the resilience of health systems to cope with climate shocks.
15.	**Gender and human rights**	The expertise involves a comprehensive understanding of how gender dynamics and human rights principles impact health

		outcomes and access to healthcare. This includes recognizing and addressing the systemic health inequities that disproportionately affect marginalized groups, including women, LGBTQ+ individuals, and other vulnerable populations; ensuring that health policies are gender-responsive and inclusive; understanding how social determinants of health, such as gender, intersect with other factors like race, socioeconomic status, and geography and applying international human rights laws and ethical principles to protect individuals' rights to health.
16.	**Engagement with for-profit entities**	The expertise involves experience in ensuring that the goals and values of the for-profit entity align with the health objectives, being well-versed in the regulatory landscape, experience in effective negotiation to create mutually beneficial agreements, building and maintaining strong relationships with for-profit partners, facilitating technology transfer and innovative practices, conducting market analysis and developing strategies that ensure the sustainability and scalability of health products.

Cross-cutting areas of expertise

17.	**Health Systems**	Expertise in health systems, including health policy, health systems strengthening, public and private sector healthcare and human resource development.
18.	**M&E/Impact:**	Experience in M&E systems, including design and appraisal of M&E indicators and systems; selection and definition of indicators and baselines; verification; reporting; evaluating market impact; evaluating public health impact and value for money, impact assessment at a strategic level and assessment of efficiency and effectiveness on operational level.

2.6   Term of Office

PRC Members are appointed for an initial term of office of three years that is renewable subject to satisfactory performance. To ensure continuity, the PRC Member replacements shall not exceed 50% of the PRC membership at any one replenishment occasion.

2.7   Remuneration and Reimbursement of Expenses

PRC Chair, Vice-Chair and PRC Members will receive an annual honorarium for their services. The travel and per diem of PRC Chair, Vice-Chair and PRC Members will be paid in accordance with established WHO rules and procedures.

2.8   Resignation or Withdrawal from the PRC

A PRC Member may withdraw from the PRC at any time upon written notification to the PRC Chair and Vice-Chair. In cases of resignation, the PRC Chair, Vice-Chair and the Secretariat go back to the shortlist of 20-24 names presented to the PRC Nominations Sub-Committee and make a recommendation to the EB for replacement. The EB will confirm the nomination by electronic vote.

PRC Membership may be terminated at any time upon written notification by the PRC Chair or Vice-Chair in consultation with the Secretariat and the EB Chair.

2.9 <u>Ad Hoc Supplemental Technical Input</u>

PRC Members' expertise in the 18 skill areas defined above in Paragraph 2.5 will ensure the committee's capacity to review the entirety of most Proposals developed for EB consideration. However, in a minority of cases – particularly where Proposals involve new products or novel intervention types – there will be a need for *ad hoc* supplemental technical input to the JRC review process.

Any need for such *ad hoc* supplemental technical input will be identified as early as possible and usually at the time of issuing a call for proposals. The selection and appointment of providers of such supplemental technical input (hereinafter referred to as "Technical Consultants") will be done by the Secretariat, in consultation with the Chair and Vice-Chair of the PRC. All Technical Consultants will be appointed in accordance with WHO's financial rules and regulations and their names included in the PRC summary record.

The focus and parameters for any supplemental technical input will be elaborated in proposal-specific TOR. The Technical Consultants' input will be provided to the JRC in the form of a written report designed to inform the JRC's wider review and deliberation.

The JRC itself remains ultimately responsible for all recommendations it makes to the EB. Technical Consultants will not participate in JRC meetings during which final recommendations are formulated by JRC Members. Technical Consultants will be held to the same standards governing conflict of interest and confidentiality as JRC Members.

3. Performance Assessment

3.1 <u>Performance assessment of PRC Members</u>

A yearly performance assessment of PRC Members will be conducted by the Chair and Vice-Chair of the PRC based on the following simple criteria of assessment:
- Regularity of attendance/ participation in PRC/JRC in-person meetings/teleconferences/discussions
- Level of participation/engagement/responsiveness
- Quality of input/recommendations
- Compliance with DOI and Confidentiality policies

The PRC Chair and Vice-Chair will share the performance assessment with the Secretariat in writing. This assessment will be complemented by self-assessment and peer-assessment done by each PRC member based on the same above assessment criteria. In cases of performance assessment/self-assessment/peer assessment revealing non-performance on any of the assessment criteria, the PRC Chair and Vice-Chair may recommend withholding the end-of the year payment of PRC Member honorarium.
Performance assessments will be used as a criterion for PRC membership renewal.

3.2 <u>Performance assessment of PRC Chair and Vice-Chair</u>

Performance assessment of the PRC Chair and Vice-Chair is based on peer assessment process. The assessment process is administered by the Secretariat at the end of each calendar year, at the same time as the performance assessment of the rest of the PRC Members. Once completed, the assessments of the PRC Chair and Vice-Chair are sent to the Board Chair and the PSC Chair by the Secretariat, having strict regard to the need to maintain confidentiality.

In addition to the criteria listed in the Paragraph 3.1, the PRC Chair and Vice-Chair are assessed against the following criteria:

- Effective facilitation of the JRC meetings leading to consensus building;
- Ability to listen and solicit contributions from other colleagues whose expertise, views, and personal and professional background are different from their own;
- Effective and timely organization of proposal and GAD review teams, ensuring the availability of the required expertise.

Performance assessments will be used as a criterion for eventual PRC Chair and Vice-Chair renewal.

The following rating scale is used for the scoring of each criteria listed in the Paragraphs 3.1 and 3.2:
1 – Agree
2 – Partially agree
3 – Disagree

4. Working procedures

4.1   PRC Members review Proposals and GAD documents made available to them by the Secretariat and provide advice based on assessment criteria and on specific issues raised by the JRC, EB and /or the Secretariat.

4.2   <u>JRC Meetings</u>

The PRC will participate in the JRC meetings which will be organized on a needs basis, on average once annually in person and twice virtually. The JRC may meet face-to-face, or virtually, as is most appropriate for the work of the JRC at that time. Where meetings are held virtually, JRC Members should make every effort to ensure that a secure connection is used and that persons not approved by the JRC Co-Chairs[5] do not listen to the proceedings.

JRC meetings will be co-chaired by the PRC Chair and the Director Strategy of Unitaid.

The JRC discussion will be based on pre-meeting assessments done by the PRC Review Teams[6] and the Secretariat Review Team separately. Both PRC and Secretariat Review Teams will use the Assessment Tool to note their scores, rationales and overall assessment of each Proposal.

The Secretariat will introduce the discussion at a JRC meeting by summarizing the call intent, specific requirements of the Area for Intervention (AfI), the outcome of the initial Level 1 and Level 2 reviews done by the Secretariat, the outcome of the partner consultations organized by the Secretariat and, if relevant, the input from technical experts as described in the Paragraph 2.9.

Both the PRC and Secretariat Review Teams will then introduce their assessments, proposal by proposal, followed by an open discussion per proposal and per

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[5] PRC Chair and Director Strategy of Unitaid serve as JRC Co-Chairs.
[6] Usually 3 -4 PRC Members constitute a PRC Review Team. The composition of the review teams is determined by the PRC Chair based on the analysis of declarations of interest, available expertise and taking into account equal distribution of workload amongst all PRC Members.

assessment area[7], moderated by the JRC Co-Chairs with the aim of arriving at agreed consensus scores, rationales, discussion on "portfolio approach" and final recommendation to the EB.

The "portfolio approach" segment of the discussion is an important part of the assessment process and should inform arriving at consensus recommendation of the JRC. This discussion will ensure the following:

- best approach to achieving full call scope, priority interventions, geographic scope coverage and impact;
- avoiding overlap and leveraging synergies =;
- balancing the burden on the Secretariat against considering smart, well-justified proposals;
- balancing strong technical approaches against community –led approaches;
- inclusion of South-based lead implementing partners;
- maximizing community and civil society engagement;
- improving climate and environmental co-benefits
- the potential for simplifying processes and grant documents; and
- smart ways for managing partnerships and synthesizing learnings into comprehensive deliverables.

The agenda for JRC meetings will be developed by the Secretariat in collaboration with the JRC Co-Chairs.

4.3. JRC Recommendations

The JRC will aim to arrive at its recommendations based on consensus. The JRC meeting agenda will contain a separate special session to review and agree on the exact final recommendations to the EB. In the unlikely and exceptional event that consensus cannot be achieved, the positions of the PRC and Secretariat will be conveyed to the EB.

4.4 Summary Record

The Summary Record of the JRC meetings will be compiled and maintained by Unitaid's Secretariat. The Summary Record will be considered and endorsed by JRC Members. In the unlikely and exceptional event that consensus cannot be achieved, the positions of the PRC and Secretariat will be conveyed to the EB.

4.5 GAD Reviews

The GAD document reviews are usually performed by the same PRC Review Team members who reviewed the initial proposal. The PRC Chair will constitute special PRC Review Teams in cases of atypical/enabler proposals and grant renewals that have not undergone the process of competitive selection under the current Unitaid Operating Model or in cases when the original PRC Review Team members are no longer at the service of the PRC. The PRC Review Teams will perform the reviews based on deskwork and teleconference/web-meetings may be organized by the PRC Review Team members at their discretion to arrive at agreed opinion/recommendations.

5. Transparency and Confidentiality

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[7] The assessment areas include rationale and strategic alignment, impact, organizational capacity, proposal design and alignment, budget, compliance and risks.

5.1 The membership, terms of reference and operating procedures of the PRC are published on the Unitaid website.

5.2 PRC Members in their advisory capacity linked to the proposal review process, may have access to certain information relating to proposal review or grant making processes, which Unitaid considers to be confidential. PRC Members are therefore required to complete and sign a general Confidentiality Undertaking form upon signing their contract and are also required to complete and sign specific Confidentiality Undertaking forms against the list of proponent organizations and their consortium members for each specific round of review.

5.3 JRC meetings will be closed to the public.

6. Declarations of Interests (DOI)

6.1 To ensure the highest integrity and public confidence in its activities, Unitaid requires that PRC Members disclose any circumstances that could give rise to a potential conflict of interest related to the proposal review process in which they will be involved.

6.2 PRC Members are required to complete and sign a general DOI form upon signing their contract and are also required to complete and sign specific DOI forms against the list of proponent organizations and their consortium members for each specific round of review.

6.3 Unitaid Secretariat will analyse the submitted DOI forms and together with the PRC Chair decide on appropriate actions to manage the declared interests in order to avoid conflict of interest situations[8].

6.4 The Secretariat will summarize all declarations made and the suggested management actions in a presentation made at the beginning of each JRC meeting. Subject to agreement of the JRC Co-Chairs, this information will then be reflected in the JRC Summary Record.

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[8] E.g. PRC Chair allocates PRC Members to PRC Review Teams only following thorough analysis of the declarations made.

Annex 1
Unitaid Proposal Process

Unitaid's operating model aims to make the grant agreement development process fast, focused and efficient, while ensuring that grant agreements are fully consistent with global health goals and help other global health partners achieve more with scarce resources.
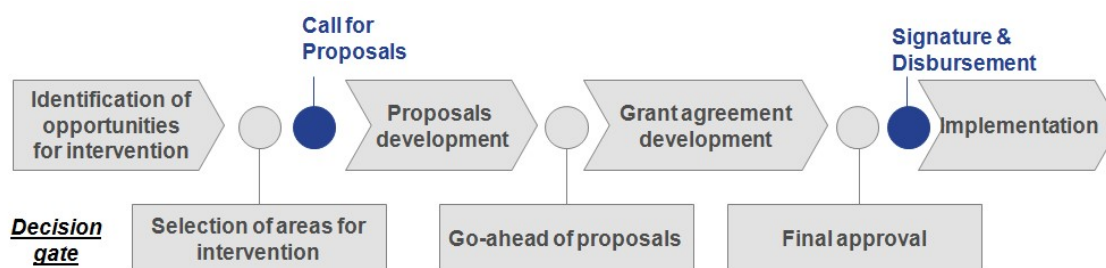
1. Areas for Intervention (AfIs)

   Unitaid identifies opportunities and areas for intervention, through internal analysis and engagement with partners and countries. Multiple targeted Calls for Proposals within selected areas for intervention are launched per year.

2. Proposal submission

   Proposals are submitted within 3 months from the call announcement date, if not specified otherwise. Complete proposals consist of the following documents:
   - Proposal form with scanned version of signed Front page
   - Annex 1: Log frame and GANTT chart template
   - Annex 2: Budget details
   - Annex 3: Organizational details and CVs of key team members
   - Annex 4: Country engagement support Letters
   - Annex 5: Declaration of relevant interest
   - Annex 6: Applicable ethics, anti-discrimination and environmental policies
   - Annex 7: Declaration regarding tobacco entities
   - Annex 8: Anti-Terrorism Declaration
   - Annex 9: Audited financial statements for the past 3 years

3. Proposal Assessment

   Proposal assessment is done in three levels. The first two levels are done by the Secretariat and only those proposals that have reached the level three stage are assessed by both the PRC and Secretariat Review Teams in parallel with the final discussion and recommendation during a JRC meeting.

   The proposals are assessed based on the following criteria:
   - Level 1
     General fit

   - Level 2
     Technical criteria
     Potential feasibility

   - Level 3

Rationale and strategic alignment
Impact
Organizational capacity
Project design and alignment
Budget
Compliance
Potential risks

4.   EB "Go-Ahead" Decision

Based on the JRC recommendation, which may contain conditions to be addressed early in the GAD process, the EB grants its "Go- Ahead" decision, which allows successful proponents to start the grant agreement development process with the Secretariat. The EB "Go-Ahead" decision involves no financial commitment from the EB.

5.   Grant Agreement Development (GAD) Process

Following notification of the "Go-Ahead", applicants will work with the Unitaid Secretariat to develop a grant agreement based on Unitaid's Standard Terms and Conditions. The grant agreement includes, but may not be limited to, a Project Plan, Budget and Logical Framework.

The PRC Members are engaged in the GAD process usually after the second iteration to ensure that the comments, conditions and recommendations made by the JRC and the EB have been addressed during the GAD process. The PRC opinion at this stage is final and no further clarifications or responses are examined.

6.   The EB Funding Decision
At the end of the GAD process, the EB makes the final funding decision following which the grant implementation starts.